7.



1. 1-(3-carboxypyridyl-2)-4-methyl-2-phenylpiperazine dihydrate.

The compound of claim 1 containing about 10.7 ± 1 weight percent water.

The compound of claim 1, wherein the compound is characterized by the following PXRD peaks: 8.4, 9.0, 10.5, 12.9, 13.7, 14.1, 15.1, 16.7, 17.8, 18.2, 18.8, 20.1, 20.9, 21.2, 22.0, 22.4, 22.9, 23.2, 23.7, 24.6, 25.1, 25.5, 26.0, 26.7, 27.0, 27.8, 28.3, 28.8, 29.4, 30.1, 31.2, 33.0, 34.2, 34.7, 36.2, 36.8, 37.8, 39.4 ± 0.2 degrees two theta.

4. The compound of claim 1, wherein the compound is characterized by the following main PXRD peaks: 9.0, 10.5, 13.7, 15.1, 20.1, 21.2, 22.0, 23.7 \pm 0.2 degrees two theta.

5. The compound of claim 1, wherein the compound is characterized by a differential thermal gravimetry thermogram having an endothermic peak at about 97 °C and a second endothermic peak at about 160 °C.

The compound of claim 1, wherein the compound is characterized by a differential thermal gravimetry thermogram having an endothermic peak at 97 °C, a weight loss of about 11 % between 27 °C and 114 °C, and a second endothermic peak at 160 °C.

A process for preparing 1-(3-carboxypyridyl-2)-4-methyl-2-phenylpiperazine dihydrate comprising the steps of:

heating a mixture of a basic salt solution of a 1-(3-carboxypyridyl-2)-4-methyl-2-phenylpiperazine and an organic liquid; and neutralizing the solution with an acid.

8. The process of claim 7, further comprising:

recovering 1-(3-carboxypyridyl-2)-4-methyl-2-phenylpiperazine dihydrate from the solution.

- 9. The process of claim 7, wherein the basic salt solution comprises a base selected from the group consisting of potassium hydroxide, sodium hydroxide, lithium hydroxide, barium hydroxide, and tetraalkylammonium hydroxide.
- 10. The process of claim 9/wherein the basic salt solution comprises potassium hydroxide.
- The process of claim 7, wherein the organic liquid is selected from the group consisting of methyl iso-butyl ketone, toluene, heptane, and mixtures thereof.

The process of claim 7, wherein the rganic liquid comprises methyl iso-butyl ketone.

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13. The process of claim, wherein the heating step comprises refluxing.

The process of plaim 7, wherein the acid is an aqueous acid solution.

15. The process of claim 14, wherein the aqueous acid solution comprises an acid selected from the group consisting of phosphoric acid, nitric acid, sulfuric acid, acetic acid and hydrochloric acid.

16. 2017

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The process of claim 14, wherein the aqueous acid solution comprises about 5-36% w/w hydrochloric acid.

A process for preparing mirtazapine comprising converting 1-(3-carboxypyridyl-2)-4-methyl-2-phenylpiperazipe dihydrate to mirtazapine.

The process of claim, wherein the converting step comprises a reducing step and a dehydrating step.

19. The process of claim 17, wherein the converting step comprises:
reducing carboxy-NMPP dihydrate to form hydroxy-NMPP; and
dehydrating the hydroxy-NMPP to form mirtazapine.